REMARKS

Status of the Claims

Upon entry of these amendments, claims 1, 5-37, 41-46, 51, 52 and 55-67, 69-70, 79-86 and 97-104 will be pending. Claims 2-4, 38-40, 47-50, 53-54, 68, 71-78 and 87-96 have been cancelled without prejudice or disclaimer. Claims 1, 6, 35-37, 67, 79-82, 84 and 86 have been amended but no new matter has been introduced. New claims 97-104, which are similar to claims 79-86 but depend (directly or indirectly) from claim 22 rather than claim 76, have also been added. Support for the new claims can be found in the application as filed. Applicants respectfully request entry of these amendments.

Provisional Election

The Examiner has required an election under 35 U.S.C. §121 of one of Groups I and II (*See*, Paper mailed March 7, 2006 at page 2). As defined by the Examiner, the claims of Group I are drawn to antibodies and kits and the claims of Group II are drawn to methods of treatment using antibodies. Applicants submit that new claims 97-104 fall within the scope of Group II. The Examiner has further required a species election from each of Group I and Group II.

For Group I, the Examiner required Applicants to elect a single combination of Specie A (a combination of VH and VL domains) and Specie B (antibody function). Specie A was defined as "a combination of a VH domain of SEQ ID NOS:48-56 and a VL Domain of SEQ ID NOS: 48-56." Specie B was defined as "1 – inhibition of binding to anthrax receptor; 2 – inhibition of binding of PA to capillary morphogenesis protein; 3 – inhibition of cleavage of PA; 4 – inhibition of heptamerization of PA63; 5 – inhibition of PA63 binding to edema factor; 6 – inhibition of PA63 binding to lethal factor; 7 – inhibition of PA-mediated translocation of EF across a cell membrane; and 8 – inhibition of PA-mediated translocation of LF across a cell membrane" (See Paper mailed March 7, 2006 at page 3).

For Group II, the Examiner required Applicants to elect a single combination of Specie A (a combination of VH and VL domains), Specie B (antibody function) and

Specie C (second agent). Species A and B were the same as the Species A and B defined above for Group I. Specie C was defined as:

> Specie C - soluble form of the anthrax receptor, soluble form the CMG2 recepro, anti-anthrax receptor antibody, anti-EF antibody, anti-LF antibody, anthrax vaccine, polyvalent form of the P1 peptide, ciprofloxacin, doxycycline, penicillin G procaine, amoxicillin, ofloxacin, levofloxacin, protease inhibitor, anti-TNF alpha antibody and anti-IL1 beta antibody. (see Paper mailed March 7, 2006 at paragraph spanning pages 3-4).

In order to be fully responsive, Applicants hereby provisionally elect, *with traverse*, the subject matter of Group I represented by pending claims 1, 5-37, 41-46, 51, 52, 55, and 67-70. Applicants further provisionally elect, *with traverse*, the combination of the VH domain and the VL domain from SEQ ID NO:53 for Specie A and Specie B8, the inhibition of PA mediated translocation of PA across a cell membrane. Each of pending claims 1, 5-21, 33-37, 41-46, 51, 52, 55, 67, and 69-70 is readable upon the elected species.

Applicants reserve the right to file one or more divisional applications directed to the non-elected groups and/or species.

Traversal of Restriction Requirement

Applicants assert that the present restriction requirement is improper because 1) the species, at least for Species set B, are not mutually exclusive; 2) generic claims are present and but are not recognized in the restriction requirement; 3) the restriction requirement, in its current form, impermissibly reads limitations into the claims and 4) it would not be a serious burden to search the inventions of the different groups and species together. A detailed discussion of these issues follows.

1) The species recited for Group I are not mutually exclusive

The Examiner asserts that the species are independent or distinct because "they lack the same function and a common core structure as essential to the disclosed utility. A search for one function will not reveal art on the other functions." (See, first full paragraph

of page 4 of the paper mailed March 7, 2006). Applicants respectfully disagree and traverse.

Preliminarily, Applicants disagree with the Examiner's assertion that the claims do not present a common core structure. Claims 35-37, 41-46, 51, 52 and 55-67, 69-70, and 79-86 all share the common core structure of amino acid residues 1-117 and 134-244 of SEQ ID NO:53, which form the VH & VL domains of the claimed antibodies or fragments thereof and are essential to the disclosed utilities in that they are responsible for the binding of the claimed antibodies or fragments thereof to PA. Moreover, claims 1, 5-34, and 97-104 encompass antibodies or fragments thereof with at least 85% identity to this common core structure and also bind to PA, and are thus based on the same common core structure. Applicants also note that, contrary to the Examiner's assertion, the antibody functions of the 8 recited "B species" are not required for each of the disclosed patentable utilities in the application. For example, an antibody according to, e.g., claim 1 or 35, may be used to detect PA in a test sample irrespective of whether the same antibody could also be used to inhibit PA-mediated translocation of LF across a cell membrane.

MPEP § 806.04(f) instructs that requirement for restriction to a single species between claims that are limited to species is improper if the claims overlap in scope. It follows then, that restriction between species that overlap in scope should also be impermissible. Applicants submit that the antibody functions listed as Species B1-B8 are not mutually exclusive. Applicants direct the Examiner to paragraphs [0004] and [0005] of the specification which describes the process by which the tripartite anthrax toxin comprised of Protective Antigen (PA), Lethal Factor (LF) and Edema Factor (EF) intoxifies cells. From this process it is apparent that, for example, an antibody that falls within species B1 or B2, by being capable of inhibiting of PA binding to the anthrax receptor (SEQ ID NO:3) or CMG2 (SEQ ID NO:42), will also inhibit downstream events such as PA mediated translocation of EF or LF across the cell membrane. Therefore, such an antibody will also fall within the scope of species B7 and B8. Similarly, an antibody that inhibits binding of PA to ATR (Specie B1) may also inhibit binding of PA to CMG2 (specie B2). Indeed, the present application discloses that the antibody described as PWD0587, the VH and VL domains of which correspond to the VH and VL domains of SEQ ID NO:53, inhibits PA binding to both ATR and CMG2 (see Figure 1 and paragraphs [0363] and [0364]. Thus, the listed species are not mutually exclusive, and restriction

between them should be impermissible. Furthermore, because the species are not mutually exclusive, a search for one function will reveal art on other functions. For these reasons, Applicants respectfully request that the restriction for the requirement of a species election from one of species B1-B8 be reconsidered and withdrawn.

2) Generic linking claims are present but are not recognized in the restriction requirement

MPEP § 806.04(d) (Revision 3, August 2005)[1] defines a generic claim as follows (in pertinent part):

> In general, a generic claim should require no material element additional to those required by the species claims, and each of the species claims must require all the limitations of the generic claim.
>
> Once a generic claim is allowable, all of the claims drawn to species in addition to the elected species which require all the limitations of the generic claim will ordinarily be allowable over the prior art in view of the allowability of the generic claim, since the additional species will depend thereon or otherwise require all of the limitations thereof.

This last paragraph quoted above describes how the presence of a generic linking claim, if allowable, acts to prevent restriction between species. This concept is outlined further in MPEP §809 which states that:

> There are a number of situations which arise in which an application has claims to two or more properly divisible inventions, so that requirement to restrict the application to one would be proper, but presented in the same case are one or more claims (generally called "linking" claims) inseparable therefrom and thus linking together the inventions otherwise divisible.
>
> Linking claims and the inventions they link together are usually either all directed to products or all directed to processes (i.e., a product claim linking properly divisible product inventions, or a process claim linking properly divisible process inventions). The most common types of linking claims which, if allowed, act to prevent restriction between inventions that can otherwise be shown to be divisible, are
>
> (A) genus claims linking species claims;
>
> (B) subcombination claims linking plural combinations.

[1] All quotes form the MPEP in this response are derived from the most current version of chapter 800: Revision 3 dated August 2005. Further, for ease of reading, "+", "<", and ">" symbols indicating revisions from prior MPEP versions have been deleted from MPEP quotations in this Response.

MPEP §809 further states that:

> The linking claims must be examined with, and thus are considered part of, the invention elected. When all claims directed to the elected invention are allowable, should any linking claim be allowable, the restriction requirement between the linked inventions ***must be withdrawn***. Any claim(s) directed to the nonelected invention(s), previously withdrawn from consideration, which depends from or requires all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability. Where the requirement for restriction in an application is predicated upon the nonallowability of generic or other type of linking claims, applicant is entitled to retain in the application claims to the nonelected invention or inventions. (emphasis added)

The second full paragraph on page 4 of the paper mailed March 7, 2006 indicates that no claims are generic. Applicants respectfully disagree.

For example, claim 1 is generic to pending claims 5-20. This is because claims 5-20, each directly or indirectly depend from claim 1, and thus clearly contain all the limitations of generic claim 1. Similarly, claim 22 is generic to claims 23-32 and 97-104, claim 35 is generic to claims 41-46, 51 and 52, and claim 56 is generic to claims 57-66 and 79-86. Arguments presented below for claim 1 would apply equally well to claims 22, 35 and 56.

Therefore, pursuant to MPEP § 809, should generic claim 1 be considered allowable, the present restriction of members of each species B1-B8 would have to be withdrawn and the non-elected species from each of species B1-B8 would have to be rejoined and examined for patentability.

Should the Examiner intend to maintain the requirement for an election of one of Species B1-B8, Applicants respectfully request that, at the very least, the restriction requirement be modified to (1) acknowledge the presence of generic linking claims 1 and 35 for Group I, as well as the presence of generic claims 22, 56 and 76 for Group II; (2) acknowledge that the full scope of generic claims 1 and 35 will be examined in conjunction with the elected Group/Specie; and (3) acknowledge that the allowance of generic linking claim 1 would result in rejoinder and examination for patentability of all species from each of species B1-B8.

3) The species election impermissibly read limitations into the claims.

In the absence of proper identification and treatment of generic linking claims (discussed above), the requirement for an election of species B1-B8 for Group I is improper because it reads limitations into the pending claims that are not there. In other words, if Applicants elect, for example, species 8, an antibody according to, for example claim 1 or 35, that inhibits PA-mediated translocation of LF across a cell membrane and the Examiner applies that election to all the claims within Elected Group I, that means the Examiner will examine the claims only insofar as the additional claims are drawn to antibody that inhibits PA-mediated translocation of LF across a cell membrane. However none of the other claims in Group I either require implicitly or recite explicitly, the limitation that the antibody must inhibit PA-mediated translocation of LF across a cell membrane. And, as noted above, such function is not required for all patentable utilities.

In this regard, the MPEP instructs that limitations may not be read into the claims which have no express basis in the claim. *See*, MPEP § 2111 ("The court explained that 'reading a claim in light of the specification, to thereby interpret limitations *explicitly* recited in the claim, is a quite different thing from 'reading limitations of the specification into a claim,' to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim.'"). Section 2111 of the MPEP further instructs that proper examination requires that the pending claims be given the "'broadest reasonable interpretation consistent with the specification.'...and broad interpretation by the Examiner reduces the possibility that the claim once issued, will be interpreted more broadly than is justified. *In re Prater* 415 F2.d 1393, 1404-5...(CCPA 1969)." Thus, Applicants submit that it would be improper to apply the species election to the all the claims of Group I.

Applicants also note that Species B2-B8 are all drawn from Markush type claims 6 and 40. Thus, Applicants wish to draw the Examiner's attention to MPEP § 803.02 which instructs that after election of a species in a Markush type claim,

> [t]he Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species....should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended....The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim.

MPEP § 803.02 indicates that should the elected species of the Markush group be found allowable, that examination will be extended until at least one member of the Markush group is found not to be allowable or, alternatively, until all the members of the Markush group (and thus the entire Markush claim) are determined to be allowable. Thus, restriction of individual members of the Markush group does not result in withdrawal of the non-elected species from consideration by the Examiner unless at least one member of the Markush group is found not to be allowable over the prior art, and no rectifying amendment or convincing argument is made by the Applicant in response. Applicants submit that search of the restricted species together would not be an undue burden (see below) and that withdrawal of the restriction requirement, at least in so far as it applies to the "B species" election, would simplify and expedite examination of the present application.

Applicants also note that MPEP § 803.02 instructs that "If a Markush claim depends from or otherwise requires all the limitations of another generic or linking claim," the procedures outlined in MPEP § 809 (described above) should be followed.

In light of the above discussion, Applicants respectfully request that the Examiner reconsider and withdraw the requirement for a species election from each of species B1-B8 for Group I.

It would not be a serious burden to search different groups or the different species together

MPEP § 803 instructs that, "[I]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." In the present situation, while the Examiner has asserted that Groups I and II are separately classified and that the claimed products could be used with different processes and *vice versa*, Applicants disagree that search of the groups together would be a serious burden as discussed below. Applicants also disagree that the combined search of the enumerated species would present a serious burden, particularly in view of the common core structure noted above.

The search for generic linking claim 1 is a search that must be performed no matter which Group/Species is elected. The search of generic claim 1 will entail a search

for prior art antibodies that specifically bind protective antigen (PA) and a query as to whether any such antibodies contain an amino acid sequence that is at least 85% identical to the amino acid sequence of amino acid residues 1-117 of SEQ ID NO:53 and an amino acid sequence that is at least 85% identical to the amino acid sequence of amino acids residues 134-244 of SEQ ID NO:53. It is necessary to perform this search no matter which species is elected or which group is elected, either because claim 1 is a generic linking claim (as it is for several claims within Group I) or because claims in Groups I and II include an antibody that falls within the scope of claim 1 as a material element.

The search of the antibody of claim 1 is all that is necessary to allow examination of all the claims and species, elected and non-elected. This is because the search of the antibody of generic linking claim 1 will uncover art pertaining to the antibody composition recited in the claims. Additionally, the search of the antibody of generic linking claim 1 is a broader search than the search for individual species, and thus such a search would necessarily identify all art relevant to each of the species. If no art is found for claim 1, then all species should be allowable over the prior art, because each of the narrower claims containing species contain all the limitations of claim 1. If claim 1 is novel, so will all the species be novel (see, MPEP § 806.04(d)). Since the search for generic linking claim 1 encompasses all the searches necessary for all the species, the combined search and examination of all species, particularly within species B1-B8, would not entail a serious burden. Accordingly, Applicants respectfully request that the requirement for species elections be reconsidered and withdrawn.

Furthermore, the search of the antibody of claim 1 will no doubt provide information regarding the methods of using said antibody; indeed, the claims of Group II either depend from the claims of Group 1 or contain all the limitations thereof. Thus, the search of the claims of Group I clearly encompasses the search for the claims of Group II. Accordingly, Applicants respectfully request that the restriction requirement of the claims into Groups I-II also be reconsidered and withdrawn.

Request for Rejoinder

The Examiner required restriction between product (Groups I) and process claims (Groups I) (Paper mailed March 7, 2006) In accordance with the decisions in *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422,

37 USPQ 2d 1663 (Fed. Cir. 1996), and the notice published in the Official Gazette on March 26, 1996 setting forth new guidelines for the treatment of restricted product and process claims (*See* 1184 OG 86). Applicants respectfully request that if the restriction requirement is made final and if the claims of Group I are found allowable, that the claim of Group II be rejoined and examined for patentability. *See* also MPEP § 821.04.

CONCLUSION

In view of the discussion above, Applicants respectfully repeat their request that the Examiner reconsider and withdraw the present restriction, particularly as regard the "B Specie" election.

If, however, the Examiner insists on maintaining the restriction requirement, then Applicants respectfully request that the restriction requirement be modified according to the following: 1) acknowledge the presence of generic linking claims 1 and 35 for Group I, as well as the presence of generic claims 22 and 56 for Group II; 2) acknowledge that generic claims 1 and 35 will be examined in conjunction with the elected Group/Species; and 3) acknowledge that the allowance of generic linking claim 1 would result in rejoinder and examination for patentability of all species from each of species B1-B8.

Applicants retain the right to petition from the restriction requirements & election of species requirements under 37 CFR § 1.144 should they be made final, either in their present form or in a modified form.

Applicants respectfully request that the above remarks be made of record in the file history of the instant application. If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required

for an extension of time under 37 CFR § 1.136 that is not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

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